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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/725,159

12/01/2003

Erning Xia

P03366

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23702

7590

07/24/2006

Bausch & Lomb Incorporated
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Rochester, NY 14604-2701

EXAMINER

VANIK, DAVID L

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,159

Applicant(s)

XIA ET AL.

Examiner

David L. Vanik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6,7,9-12 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-4, 6-7, 9-12, 16-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of the Applicant's Remarks and Amended Claims filed on 2/25/2006. Additionally, receipt is acknowledged of Applicant's Request for Continued Examination filed on 5/24/2006.

The 35 USC §102 rejections over US Patent 6,274,133 ('133) are hereby **maintained**. As a result of Applicant's Amendment, the 35 USC §112 rejections are hereby **withdrawn**.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-4, 6-7, 9-12, 16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent 6,274,133 ('133).

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'133 disclose a method for treating a contact lens with a solution (abstract). The method comprises contacting the surface of a contact lens with a solution comprising a cationic cellulose polymer, a tonicity agent, and a buffering agent (claim 1). Cellulose polymers are a well-known example of polysaccharides. According to '133, a wetting agent can be added to the contact lens solution (Claims 4-5). The wetting agent can comprise mono or disaccharides (claim 5). Thus, the contact lens solution advanced by '133 comprises a cationic polysaccharide and a saccharide. It should be noted that the examiner is interpreting a contact lens as a type of medical device.

It is the examiner's position that, inherently, the contact lens solution advanced by '133 would eliminate a "microbial burden" when soaked with the contact lens. Since the essential elements of the '133 composition are identical to the instant composition (that is, a contact solution comprising a cationic polysaccharide and a saccharide), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '133 anticipates the compositions enumerated in the instant claim set.

The claims are therefore anticipated by US patent 6,274,133 ('133).

Arguments

Applicant's remarks filed on 2/15/2006 have been fully considered, but it is the examiner's position that they do not place the application as written in condition for

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allowance. Specifically, Claims 1-3 of '133 comprise a method of treating contact lenses with a cationic cellulose polymer, a polysaccharide, and a mono or disaccharide. These claims, as written, do not require the presence of a preservative or antimicrobial agent. Although the examiner acknowledges the suggestion that the composition advanced by '133 will comprise a disinfecting amount of a preservative or antimicrobial agent, claims 1-13 of '133, as written, do not require the presence of an additional microbial agent. Moreover, the amounts of the polysaccharide (0.01 to 1.0 %) and the mono or disaccharide wetting agents (0.01 to 2%) are within the range of the instant application, suggesting that they are present in such an amount for solution preservation. Barring a showing of unexpected results, it is the examiner's position that '133 anticipates the instant claim set. It should be noted that new remarks were not filed in conjunction with the RCE. As such, the 2/15/2006 are the most recent remarks filed in this application.

NEW REJECTIONS:

The following is a list of new rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4, 6-7, 9-12, 16-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant Claims 20-21 are drawn to a method of treating a contact lens or medical device comprising contacting the surface of either a contact lens or medical device with a preserving agent "consisting essentially of one or more saccharides in combination with one or more cationic polysaccharides wherein the saccharides and cationic polysaccharides are in an amount effective for solution preservation." After carefully reviewing the instant disclosure, the examiner respectfully submits that the claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the instant specification and examples include a preserving agent other than a combination of saccharides and cationic polysaccharides. As set forth in Tables 6, 8, and 12 (pages 23, 27, and 35 of the instant specification), the monosaccharide/cationic polysaccharide-based compositions each contain 0.050% EDTA. Moreover, paragraph 0027 of the instant specification note that the compositions comprise between 0.01 to about 2% by weight of EDTA, but that this amount does not "increase the formulation's preservation efficacy."

EDTA is a well-known contact solution preservative agent (See US 5,382,599, column 2, lines 6 – 31 and column 3, lines 47-49; US 5,141,665, column 3, lines 31 – 56; and US 4,436,730, column 7, lines 46 – 49). Additionally, only a small amount of EDTA need be present in a contact solution in order to impart a preservation effect on said solution (See US 5,382,599, column 2, lines 6 – 31 and column 3, lines 47-49; US 5,141,665, column 3, lines 31 – 56; and US 4,436,730, column 7, lines 46 – 49). Thus, despite the statement in paragraph 0027 of the instant specification that EDTA does not increase the formulation's preservation efficacy, the examiner respectfully submits that 0.050% by weight of EDTA does in fact increase preservation efficacy in a contact solution composition (See US 5,382,599, column 2, lines 6 – 31 and column 3, lines 47-49; US 5,141,665, column 3, lines 31 – 56; and US 4,436,730, column 7, lines 46 – 49). As a result, because the instant contact solutions appear to require the presence of EDTA and the instant disclosure does not explicitly set forth a composition comprising only saccharides and cationic polysaccharides, the examiner respectfully submits that the instant specification does not comply with the written description limitation with respect to the "consisting essentially of" claim language that is enumerated in the instant claims 20-21.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4, 6-7, 9-12, 16-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a limited class of saccharides and cationic polysaccharides, such as Polymer JR, Methyl- α -D-glucopyranoside, and D-glucose, does not reasonably provide enablement for the generic class of saccharides and cationic polysaccharides (See Tables 6, 8, and 12 on pages 23, 27, and 35 of the instant specification). The examiner respectfully submits that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The limitations "saccharides and cationic polysaccharides" are extremely broad and encompass an extremely large class of agents. After carefully reviewing the instant specification, the instant examples are directed towards a specific combination of saccharides and cationic polysaccharides. As set forth in Tables 6, 8, and 12, only a limited number of saccharides and cationic polysaccharides have been tested in combination with one another. Specifically, Polymer JR was used as a cationic polysaccharide, while Methyl- α -D-glucopyranoside and D-glucose were tested as saccharides (pages 23, 27, and 35 of the instant specification). Given the limited saccharide/cationic polysaccharide combinations set forth in the instant specification, the examiner respectfully submits that one of ordinary skill in the art would be faced with an undue experimental burden in attempting to practice the invention commensurate in scope with the claims. The prior art further supports the idea that an ordinary practitioner would not be able to practice the instant invention commensurate in scope with the instant claim set. For example, US 4,436,730 ('730) describe a composition

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comprising a saccharide (hydroxyl cellulose), with a cationic polysaccharide (JR-400 and JR-30M), and a preservative agent, benzalkonium chloride (Examples 5-6). Thus, '730 appears to require the addition of a preservative agent, benzalkonium chloride, to the saccharide/cationic polysaccharide composition (Examples 5-6). Considering this, the examiner respectfully submits that one of ordinary skill in the art would need to undergo detailed experimentation (undue) in order to determine which saccharide/cationic polysaccharide combinations are capable of exhibiting a preservative effect without the addition of an additional preservative agent, such as benzalkonium chloride or EDTA.

Correspondence

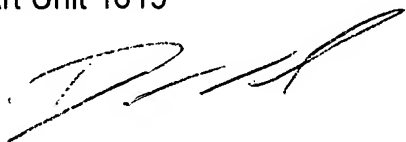
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

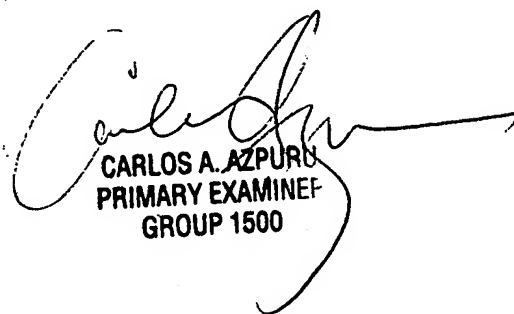
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615



7/18/06



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